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OCT 25 2012

K122299 - 510(k) Summary

This summary of safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 27, 2012

1. Submitter:

Submitted by:	**TransEnterix, Inc.** 635 Davis Drive, Suite 300 Durham, NC 27713 TEL: 919-765-8420 FAX: 919-765-8459
Contact:	Tammy Carrea VP Quality and Regulatory Affairs

2. Device:

Propriety Name	SPIDER® Flexible Surgical Instruments: Flex Monopolar Graspers, Wavy Ratcheted Flex Monopolar Graspers, Serrated Ratcheted Flex Monopolar Maryland Dissectors Flex Monopolar Shears
Common Name	Electrosurgical Monopolar Surgical Instrument
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification:	Class II, 21 CFR 878.4400
Product Code:	GEI

3. Predicate Devices:

Class	Manufacturer	510(k) Number	Device Name/Description
II	TransEnterix	K091697 K102646	SPIDER® Flexible Instruments: Maryland Dissector, Graspers (Blunt nose), Shears
II	Covidien	K091869	SILS™ Clincher, Graspers, Dissector, Shears

4. Description:

The SPIDER® Flexible Monopolar Instruments are surgical instruments used to facilitate laparoscopic surgery. The instruments are a part of the SPIDER® Flexible Surgical

Instruments family. They are intended for use with the SPIDER® Single Port Device. The instruments may be used with or without electrocautery.

The flexible electrocautery instruments are pre-sterilized, single use, disposable devices. The devices have a ring handle with ratchets where applicable, a rotation knob for rotating the shaft and distal tips, an electrocautery post for cable connection to an electrosurgical generator, a flexible shaft, and distal tips to manipulate tissue. The instruments may be used without connecting to a power source. However, when connected by a standard cable to an electrosurgical generator, the instruments may be used for cutting and coagulation of tissue. The instrument set includes:

- Flexible graspers for grasping tissue
- Flexible shears for cutting tissue
- Flexible dissectors for dissecting tissue

5. Indications for Use:

The SPIDER® Surgical Instruments are intended for use in minimally invasive abdominal laparoscopic surgical procedures for grasping, mobilizing, dissecting, retracting, cutting, cauterizing, ligating, suction/irrigation and other manipulation of tissues and vessels during laparoscopic procedures.

6. Comparison of Technological Characteristics with Predicate:

The SPIDER® Flexible Monopolar Surgical Instruments have the same intended use and function of other currently marketed laparoscopic and endoscopic surgical instruments, specifically the SPIDER® Surgical Instruments cleared in K091697. Like the predicates the instruments have the same or similar end effector/jaw/tip designs. The devices achieve the same function using the same modes of action. The flexible instruments are passed through the SPIDER®'s instrument delivery tubes (IDTs) and advanced to the surgical site in exactly in the same manner as other previously cleared SPIDER® surgical instruments.

The SPIDER® Flexible Monopolar Instruments utilize the same or similar design, dimensions, materials of construction, packaging and sterilization as that of the SPIDER® Surgical Instruments in K091697. Similar to the predicate devices the SPIDER® Flexible Monopolar Instruments are provided pre-sterilized, are disposable, and are single use devices.

The electrocautery features of the SPIDER® Flexible Monopolar Surgical Instruments are similar to those of the SILS™ Dissector and Shears from K091869. Both device designs are monopolar and include a post for cable connection to an electrosurgical generator. Both device designs are utilized with single port laparoscopic access systems.

Any technological differences between the SPIDER® Flexible Monopolar Surgical Instruments and the predicates have been mitigated via testing. The SPIDER® Flexible Monopolar Surgical Instruments do not introduce any new issues of safety or effectiveness compared to other similar laparoscopic or endoscopic surgical devices currently marketed.

7. Performance Data:

The SPIDER® Flexible Monopolar Surgical Instruments have been functionally tested and found to perform their intended functions for laparoscopic surgical procedures as well as their electrocautery functions and have been tested for reliability. The devices have also been tested with the SPIDER® device and found to meet the internal acceptance criteria for system compatibility with the SPIDER® platform.

Gamma sterility testing has been conducted for the SPIDER® Flexible Instruments Family which includes the SPIDER® Flexible Monopolar Instruments and has been shown to achieve a sterility assurance level of $1x10^{-6}$. The devices were verified as sterile via a dose audit study in accordance with ISO 11137-1, ISO 11137-2, and ISO 11137-3. In addition, the sterile barrier packaging has been tested for the SPIDER® Flexible Instruments family in accordance with ISO 11607-1 and 11607-2 and ASTM F1980-07 and has been found to maintain sterility during shelf life testing. The SPIDER® Flexible Monopolar Instruments have likewise been tested for functionality over time and have been found to maintain performance in accordance with the design specifications.

The SPIDER® Instruments have been tested for biocompatibility in accordance with ISO 10993-1 based on type and duration of contact to assure that they are non-cytoxic, non-irritating and non-sensitizing.

The SPIDER® Flexible Monopolar Instruments have been evaluated and/or tested for compliance to the medical electrical safety standards IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2 and found to be compliant. The device insulation has also been tested using high potential test (HIPOT) and dielectric withstand testing to assure that the insulation maintains its properties and does not breakdown.

The SPIDER® Flexible Monopolar Surgical Instruments have been tested in a pre-clinical swine study to evaluate their performance and success in laparoscopic procedures. The study found that the SPIDER® Flexible Monopolar Instruments performed as intended. When compared to the predicate devices, the SPIDER® Flexible Monopolar Instruments do not incorporate any significant technological differences that affect safety and efficacy, therefore, clinical data was not deemed necessary for evaluation of substantial equivalence.

These verification and validation test results are sufficient to demonstrate safety and effectiveness compared to predicate devices used in standard laparoscopic surgical techniques. Any minor technological differences in the design or materials of the SPIDER® Surgical Instruments have been evaluated and found to present no new issues of safety and effectiveness.

8. Conclusion:

The conclusion drawn from the test data is that the SPIDER® Flexible Monopolar Surgical Instruments are as safe and effective as the predicate devices, have the same intended use as the predicates, perform similarly to other legally marketed predicate devices for laparoscopic surgery, and do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 25 2012

Transenterix, Incorporated
% Ms. Tammy B. Carrea
Vice President, Quality and Regulatory Affairs
635 Davis Drive, Suite 300
Durham, North Carolina 27713

Re: K122299
Trade/Device Name: SPIDER®(Single Port Instrument Delivery Extended Reach) Surgical Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 27, 2012
Received: July 31, 2012

Dear Ms. Carrea:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) No. K122299

If known

Indications For Use Statement

Device Name: **SPIDER® (Single Port Instrument Delivery Extended Reach) Surgical Instruments**

Indications For Use:

The SPIDER® Surgical Instruments are intended for use in minimally invasive abdominal laparoscopic surgical procedures for grasping, mobilizing, dissecting, retracting, cutting, cauterizing, ligating, suction/irrigation and other manipulation of tissues and vessels during laparoscopic procedures.

Neil R P Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122299

Prescription Use	x	AND/OR	Over-The-Counter Use	
(Per 21 CFR 801 Subpart D)			(Per 21 CFR 801 Subpart C)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122299